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10/686,053	10/14/2003	Michael E. Jolley	02-1106-A	7002

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,053	JOLLEY ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 14-20* is/are pending in the application.

4a) Of the above claim(s) *14-18 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-8 and 19* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

1. This Office action is responsive to Applicant's response filed October 18, 2007. Claims 1-8 and 19 are under examination.

Rejection Withdrawn

2. In view of Applicant's response the following rejection is with drawn rejection of claim 5 under 35 U.S.C. 103(a) for the reasons set forth on pages 5-6, paragraph 4 of the previous Office Action.

Rejections Maintained

3. The rejection is maintained for claims 1-4, 6-8 and 19 under 35 U.S.C. 103(a) for the reasons set forth on pages 3-5, paragraph 3 of the previous Office Action.

The rejection is reiterated below:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The claims are rejected under 35 U.S.C. 103(a) as unpatentable over Bolz *(U.S. Patent No.4,067,959 published January 10,1978)* in view of Nasir et al *(Proceedings One Hundred and Fourth Annual Meeting of the United States Animal Health Association, October 20-27, 2000, Birmingham, AL)*.

The claims are drawn to a method for detecting *Salmonella* antigens in a sample, said method comprising the steps of combining said sample with a tracer an anti-*Salmonella* antibody to form an assay mixture said tracer comprising a fluorophore

conjugated to an oligosaccharide from a *Salmonella* cell wall lipopolysaccharide said tracer being able to bind to said anti-*Salmonella* antibody to produce a detectable change in fluorescence polarization and measuring the fluorescence polarization of said assay mixture to obtain a measured fluorescence polarization value wherein said measured fluorescence polarization value is related to the concentration of *Salmonella* antigens in said sample.

Bolz teaches a method of detecting antigens in a sample comprising contacting the antibodies specific to the antigen with the sample containing the antigen (see the Abstract and columns 5-6). Bolz et al teach that this method is performed in assay format (see the Abstract). Bolz teaches that the method of the invention includes using fluorogen labels for detection (see the Abstract). Bolz teaches that the antigen or antibody can be placed on as solid support surface depending upon which is the target molecule in the sample (See the Abstract).

Bolz do not teach using a tracer comprising a fluorophore conjugated to an oligosaccharide from *Salmonella* cell wall lipopolysaccharides or the use of fluorescence polarization.

Nasir et al teach a detecting using fluorescence polarization to detect *Salmonella enteritidis* infections in chickens by using the O -polysaccharide of S. enteritidis and an ELISA with an S. enteritidis flagellin antigen (see the Abstract). Nasir et al teach that the fluorescein used in the method is isothiocynate isomer (Materials and Methods, Section 2). Nasir et al teach that serum samples (cultured samples) as well as egg yolk (food product) were tested for *Salmonella* (Section 2.5). Nasir et al teach that a blank serum reading was taken which included a diluted tracer added and mixed and the fluorescence polarization value taken (see the Abstract). Nasir et al teach that a positive sample was indicated by a reading of 10mP higher than that of the tracer buffer (see the Abstract). Therefore, Nasir et al teach the claim limitations "the method of claim 1, wherein combining said sample with a tracer and an anti-*Salmonella* antibody to form an assay mixture comprises combining said sample with anti-*Salmonella* antibody to provide a bank mixture and combining said blank with said tracer to provide said assay mixture", "measuring the fluorescence polarization of said blank mixture to provide a blank fluorescence polarization value" and subtracting said blank polarization value from said measured fluorescence polarization value to provide a blank-corrected fluorescence polarization value, wherein said measured fluorescence polarization value is related to the concentration of *Salmonella* antigens in said sample" because these claim limitations are necessarily taught by using fluorescence polarization.

It would have been *prima facie* obvious at the time the invention was made to modify the method of detecting as taught by Bolz to include a tracer prepared from the O-polysaccharide of *S. enteritidis* and an immunoassay (ELISA) format with an *S. enteritidis* flagellin antigen according to the teachings of Nasir et al because Nasir et al teach that fluorescence polarization is highly specific, sensitive and an accurate method in which to detect *Salmonella* in biological samples. It would be expected absent evidence to the contrary that a method of detecting antigen can be performed by combining antibodies specific for the target antigen (e.g. *Salmonella)* and a tracer

because Nasir et al has demonstrated the immune complex formed by the contact of the antibodies and the antigen are detectable by fluorescence polarization, thereby accurately detecting poultry samples that are infected with *Salmonella.*

Applicant's Arguments

Applicant urges that Bolz teaches a method of detecting antigens in a sample and includes the use of fluorescent labels for detection. Applicant urges that the antigen is detected in the sample when the fluorophore is attached to the antibody. Applicant urges that the claim 1 recites the used of fluorescently labeled antigen, a tracer comprising fluorophore conjugated to an oligosaccharide from a *Salmonella* cell wall lipopolysaccharide. Applicant urges that Bolz fails to teach the use of a fluorescently labeled antigen.

Applicant urges that Nasir et al fail to make up for the deficiency in Bolz because Nasir teaches the use of fluorescence polarization to detect antibodies to *Salmonella*, not Salmonella antigens. Applicant urges that that if one of ordinary skill in the art would modified Nasir et al' s fluorescence polarization assay to detect *Salmonella* antigens, he or she would have used fluorescently labeled antibody in the place of Nasir's fluorescently labeled antigen. Applicant urges that one of ordinary skill in the art would not arrive at the claimed invention based on the combination of prior art teachings. Applicant urges that a person of ordinary skill would have used a fluorescently labeled antibody rather than the fluorescently labeled antigen (tracer) recited in claim 1.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed October 18, 2007 have been fully considered but they are not persuasive. Bolz teaches both methods of detecting antigens as well as methods of detecting antibodies. Boltz teaches that methods that the antigen or antibody can be fluorescently labeled (column 4). Bolz teaches using fluorescein isothiocyanate in the assays of the invention (column 2). Bolz teaches that the assay used to detected antigens or antibodies can be reversed depending on which component is being detected in the sample (column 2). Bolz teaches fluorescently labeled antigen or antibodies depending on the component detected in the sample (column 2). Bolz does not teach a fluorophore conjugated to an oligosaccharide from *Salmonella* cell wall lipopolysaccharides. However, Nasir et al teach that fluorescence polarization is used to detect *Salmonella enteritidis* infection in chickens using the O-polysaccharide of *S. enteritidis*. Nasir et al teach that assays based on fluorescence polarization are rapid, sensitive and cost effective (Results and Discussion section). One of ordinary skill in the art would be motivated combine a tracer comprising a fluorophore conjugated to an oligosaccharide from *Salmonella* cell wall lipopolysaccharides and an anti- *Salmonella* antibody based upon obvious to try, it should be noted that "obvious to try" is proper when there is a finding of a recognized problem or need in the art including a design need or market pressure to solve a problem, a finding that there has been a finite number of identified predictable potential solutions and a finding that one of ordinary skill in the art could have pursed the known potential options with a reasonable expectation of success. See KSR International Co. v. Teleflex Inc., 220 U.S. -, 82 USPQ2d 1385 (2007). In the instant case, the prior art

has taught that there is a need to produce a method of detecting *Salmonella* in sample that is sensitive, specific and not expensive, time consuming or cumbersome. See Nasir, Introduction. Bolz teaches immunoassays comprising *fluorescently labeled antigen or antibodies* (e.g. fluorescein isothiocyanate antigen or antibody) (column 2). Nasir et al teach that fluorescence polarization using is O-polysaccharide of *S. enteriditis* is a rapid, sensitive and cost effective way to detect antibodies to *Salmonella enteriditis* infection in chickens. Based on the long felt need in the art to develop an effective, sensitive, specific and rapid test to detect *Salmonella* in samples, it would be obvious of one of ordinary skill in the art to combine a tracer comprising the fluorophore conjugated to an oligosaccharide from *Salmonella cell* wall lipopolysaccharide (the tracer) with anti-*Salmonella* antibodies to form an assay in a method of detecting *Salmonella* antigens. This motivation is based on the teachings of Nasir et al which disclose that the fluorescence polarization using is O-polysaccharide of *S. enteriditis* is a rapid, sensitive and cost effective way to detect antibodies to *Salmonella enteriditis* infection in chickens coupled with the teachings of Bolz that disclose that *both antigens or antibodies* can be labeled with florescent labels such as isothiocyanate to detect bacteria in samples. In accordance with KSR International Co. v. Teleflex Inc., 220 U.S. -, 82 USPQ2d 1385 (2007) the standard of "obvious to try" is proper and provides one of skill in the art with the motivation to combine the teachings of the prior art to arrive at the claimed invention.

Thus, it would be obvious to apply a known technique to be used in a known method that is ready for improvement to yield predictable results.

Additionally, *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007), discloses that it is obvious to combine prior art elements according to known method to yield predictable results. Thus, the prior art references as combined provided a *prima facie* case of obviousness absent evidence to the contrary.

Status of Claims

4. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vanessa L. Ford
Biotechnology Patent Examiner
January 5, 2008

NITA MINNIFIELD
PRIMARY EXAMINER